



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,775	08/18/2003	Oystein Lie	066849-019	4144
41552	7590	10/12/2006	EXAMINER	
MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			SHAW, AMANDA MARIE	
			ART UNIT	PAPER NUMBER

1634

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TH

Office Action Summary	Application No. 10/643,775	Applicant(s) LIE ET AL.	
	Examiner Amanda M. Shaw	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 13-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-12, 38-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/31/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-62 are currently pending. Applicant's election with traverse of Group II (Claims 11, 12, and 38-62) in the reply filed on July 5, 2006 is acknowledged. Since the applicant did not provide reasons for the traversal, the requirement is still deemed proper and is therefore made **FINAL**. Claims 1-10 and 13-37 have withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim.

It is noted that Applicants have further elected to have SEQ ID Nos 183-188 to be searched. Claims 11-12, 38-39, and 54-55 are either missing SEQ ID Nos or depend on claims which are missing SEQ ID Nos. Based on the number of sequences elected by the applicant it is impossible for the examiner to determine which sequence belongs in each claim. Additionally it is noted that Claims 12 and 49 are in improper form because a multiple dependent claim cannot depend from any other multiple dependent claims. See MPEP § 608.01(n). Accordingly, claims 11-12, 38-39, and 54-55 have not been further treated on the merits.

Accordingly, Claims 40-53 and 56-62 have been examined herein.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50-58 are indefinite over the recitation of the phrase "said distinct populations of origin" in claim 50. There is insufficient antecedent basis for this limitation in the claim.

Claims 50-58 are indefinite over the recitation of the phrase "corresponding to each of said distinct populations." Corresponding is not an art recognized term to describe the relationship between a nucleic acid sequence and a population. Because the term "corresponding" has not been clearly defined in the specification and because there is no art recognized definition for this term as it relates to nucleic acid and amino acid sequences, one of skill in the art cannot determine the meets and bounds of the claimed subject matter.

Claim 59 is indefinite over the recitation of the phrase "the absence of". There is insufficient antecedent basis for this limitation in the claim.

Claim 60 is indefinite over the recitation of the phrase "said population". There is insufficient antecedent basis for this limitation in the claim.

Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1634

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40-43, 45-46, 50-52, and 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Reilly et al (Animal Genetics 1998).

Regarding Claims 40-42 O'Reilly et al teach a method wherein parentage of 792 Atlantic salmon were determined using microsatellites. Several measures of locus variability and information content were calculated for microsatellite data from the 24 parents in this study. Parentage was determined by comparing alleles at a give locus from each offspring with alleles from each of the potential parental crosses (Page 363-364). In the instant case the information collected on the parents in this study is being interpreted as a database because by definition a database is any collection of stored data.

Regarding Claim 43 O'Rielly et al teach that twelve mature female and 12 mature male Atlantic salmon were used. Several measures of locus variability and information content were calculated for microsatellite data from the 24 parents in this study. Therefore there was genotype information for every potential parent Page 364).

Regarding Claims 45 and 46 O'Rielly et al analyzed Atlantic Salmon which belong to the family Salmonidae and the species *Salmo salar* (Page 363).

Regarding Claim 50 O'Rielly et al teach a method wherein blood and muscle tissue was taken from the Atlantic Salmon and the DNA was isolated and purified prior to DNA typing. Microsatellite variation was surveyed at one dinucleotide (Ssa85) and three tetranucleotide loci (Ssa171, Ssa197, and Ssa202) (Page 364).

Regarding Claim 51 O'Rielly et al teach that twelve mature female and 12 mature male Atlantic salmon were obtained in November 1989 from a managed broodstock line from the Salmon Genetic Research Program, St Andrews, New Brunswick (Page 364).

Regarding Claim 52 O'Rielly et al teach that the genetic markers being looked at were microsatellites. Microsatellite variation was surveyed at one dinucleotide (Ssa85) and three tetranucleotide loci (Ssa171, Ssa197, and Ssa202) (Page 364).

Regarding Claim 59 O'Rielly et al teach a method wherein the absence of a match excludes said candidate genotypes as the origin of the said sample. Specifically O'Rielly et al teach that samples of offspring that did not match any of the 12 sets of parents were analyzed further to identify the source of the mismatch or incompatibility (Page 365).

Regarding Claim 60 O'Rielly et al collected information on the parent genotypes of the Atlantic salmon (Page 364). In the instant case the information collected on the parents in this study is being interpreted as a database because by definition a database is any collection of stored data.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1634

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Reilly et al (Animal Genetics 1998) in view of Agresti (Aquaculture 2000).

The teachings of O'Reilly et al are presented above in paragraph 4.

Regarding Claims 42 and 45-46 O'Reilly et al do not teach a method wherein the candidate parent genotypes belong to at least two different species and the species is *Oreochromis niloticus* (Nile Tilapia).

However Agresti et al teach a method for deriving genetically superior tilapia produced from inter crossing five different species of fish: *Oreochromis niloticus* (Nile Tilapia), *Oreochromis aureus*, *Oreochromis mossambicus*, and *Sarotherodon galilaeus*. A genomic map has been created for each of the parents using microsatellite and AFLP DNA markers (Abstract). Agresti et al teaches that these markers can be used to track the parentage of crosses between the different species of Tilapia (Page 54).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the method of O'Reilly et al to determine parentage of tilapia when the candidate parent genotypes belong to more than one species of tilapia as suggested by Agresti et al for the benefit of being able to distinguish between species of tilapia which can not be distinguished based on morphology alone. Further the prior art of Rico (Proceedings: Biological Sciences) et al teach that they studied the conservation of microsatellites among distantly related

Art Unit: 1634

species of fish and patterns of cross species polymorphisms. Specifically they used primer pairs from 18 microsatellite loci on a panel of different fish species. Rico et al teach that microsatellites are often hypervariable in number and length and that the flanking nucleotides of the microsatellite regions are also polymorphic. Thus studying microsatellites and the regions which flank microsatellites have become an important source of polymorphic genetic markers for parentage testing (Abstract, page 549, and Table 2).

5. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Reilly et al (Animal Genetics 1998) in view of Garcia de Leon (Aquaculture 1998).

The teachings of O'Reilly et al are presented above in paragraph 3.

Regarding Claim 49 O'Reilly et al do not teach a method wherein the sample and candidate parent genotypes belong to a species selected from the group consisting of rainbow trout, halibut, sea bass and Atlantic cod.

However Garcia de Leon et al teach a method in which microsatellite markers are used to determine parentage in sea bass (Abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the method of O'Reilly et al to sea bass for the benefit of being able to study an additional fish.

6. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Reilly et al (Animal Genetics 1998) in view of Fries (Nature 2001).

The teachings of O' Rielly et al are presented above in paragraph 3.

Regarding Claim 53 O' Rielly et al does not teach that the method wherein the genetic markers are SNPs.

However, Fries et al teach a method for verification of identity and parentage using a standardized set of single nucleotide polymorphisms as an alternative to microsatellite analyses (Page 508).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of O' Rielly et al by using SNPs as suggested by Fries because SNPs have a low mutation rate, are suitable for standardization, and they do not require a specific typing platform.

7. Claim 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over O' Reilly et al (Animal Genetics 1998), Fries et al (Nature 2001), and in further of Cox (US Patent 6406847 Filed 1999).

The teachings of O' Rielly et al and Fries et al are presented above in paragraphs 3 and 6.

Regarding Claims 56-58 the combined references do not teach that the method of identifying the SNP is performed using an oligonucleotide ligation assay (OLA) or using a hybridization assay on a DNA chip.

However, Cox et al teach that there are multiple methods such as chip hybridization and oligonucleotide ligation assay (OLA) that have been developed for genotyping SNPs (Column 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of O'Reilly et al by detecting the SNPs using OLA or chip hybridization as suggested by Cox because both of these procedures were routinely used for genotyping SNPs at the time of the presently claimed invention.

8. Claims 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Reilly et al (Animal Genetics 1998) in view of Dodds (US Patent 6287254 Filed 1999).

The teachings of O'Reilly et al are presented above in paragraph 3.

Regarding Claims 61-62 O'Reilly does not teach that the database is capable of instantaneously comparing the sample genotype to the collection of genotypes and that the database is accessible through the Internet.

However, Dodds et al teach a genotype database which stores data which is in the category of mostly genotype or genetic information. The information in the databases is then used to build computer driven statistical models. The computer network may conveniently include the Internet (Column 7).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of O'Reilly et al by storing the

Art Unit: 1634

information in a computer that is connected to the internet as suggested by Dodds for the benefit of being able to share the information obtained from genotyping locally, regionally, nationally, and globally (Column 3).

Double Patenting

9. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 40-62 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 38-61 of copending Application No. 10/349331. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

10. No Claims are allowed.

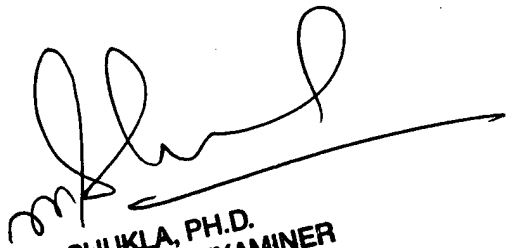
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If

Art Unit: 1634

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634



RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER